BMJ Open

Advanced consent for participation in acute care randomised control trials: protocol for a scoping review

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To cite: Niznick N, Lun R, Dewar B, *et al*. Advanced consent for participation in acute care randomised control trials: protocol for a scoping review. *BMJ Open* 2020;**10**:e039172. doi:10.1136/bmjopen-2020-039172

► Prepublication history and additional material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2020-039172).

Received 07 April 2020
Revised 02 September 2020
Accepted 29 September 2020

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ABSTRACT

Introduction Informed consent is essential to clinical research, though obtaining informed consent for participation in research for emergency conditions is challenging. Adapted consent methods include consent from a substitute-decision maker, deferral of consent and waiver of consent. A novel approach is to use advanced consent, where a potential participant provides consent in the present in the event that they become eligible for enrolment into a future study. This scoping review will map and synthesise the literature on the use of advanced consent for participation and enrolment in randomised control trials for emergency conditions.

Methods and analysis Guided by Arksey and O'Malley's scoping review methodology framework, we will search electronic databases (Medline, Embase, Web of Science and the Cochrane Register of Clinical Trials), the grey literature sources and reference lists of relevant studies. Eligible studies will include English language articles that discuss, examine or employ the use of advanced consent for enrolment in randomised control trials, specifically related to emergency conditions or emergency treatment. Diverse types of articles will be eligible for inclusion, including peer-reviewed qualitative and quantitative studies such as randomised control trials, observational studies, surveys, systematic reviews, as well as narrative reviews and ethics papers. Studies will be screened by two independent reviewers to determine eligibility for inclusion. Data on bibliographic information, study characteristics and methodology, and reported results, specifically author disposition, will be extracted and described using qualitative analysis.

Ethics and dissemination Formal ethics review is not required as primary data will not be collected. The findings of this study will be disseminated through a peer-reviewed publication. The findings of this study will help identify knowledge gaps that may guide areas for future research and may aid in the design of future clinical trials using advanced consent.

Strengths and limitations of this study

- This is a novel review looking at the use of advanced consent for participation in research.
- The eligibility criteria for this study is broad and includes articles with diverse research methodology, which will allow thorough mapping of the literature on this topic.
- Given the heterogeneity of articles eligible for inclusion in the present scoping review, quality assessment of the included articles will not be possible and will not be performed.

INTRODUCTION

Informed consent, in which a patient agrees to participate in research after having received a thorough explanation of the potential risks and benefits, is an essential component of modern clinical research. However, obtaining informed consent for participation in research is particularly challenging under emergency conditions.[1 2] Patients are often incapacitated due to the nature of the medical emergency. Moreover, decision-making needs to happen quickly, and so patients or their representatives are unlikely to have sufficient time to consider all the potentially relevant information, even if they were capable.[1] While substitute decision-makers may consent on behalf of eligible patients, practices surrounding their use vary widely between and within countries.[3–5] Furthermore, only 20%–30% of patients arrive in the emergency department accompanied by a substitute decision-maker.[6] Finally, relying on substitute decision-makers to consent on patients' behalves introduces confounding variables that may limit a study's generalisability and validity.[7] Other approaches, such as the use of deferral of consent or waiver of consent, remove the patient from decision-making, and may not be popular with patients.[8]

A novel approach to this situation is to use advanced consent. Advanced consent for research occurs when a potential participant is identified as being eligible for a study in the future and gives consent contingent on meeting the inclusion criteria at a later date, which could occur when the participant is no longer able to provide consent.[9 10] Advanced consent may be specific to a particular trial or may be a reflection of values to guide researchers in general about the patient's

desire to participate in research. Historically, this process has mainly been used for research in progressive diseases, such as dementia.[11–14] Though advanced consent may appear challenging to apply to emergency conditions given their unpredictable nature, there is still an opportunity to obtain advanced consent for research from populations with risk factors for certain emergency conditions such as ischaemic stroke, intracerebral haemorrhage (ICH), status epilepticus, acute coronary syndrome, or arrhythmias, among others.[9]

We seek to determine what research has been done on the use of advanced consent for research in emergency conditions. The main objective of this scoping review is to identify, map and synthesise the literature on the use of advanced consent for participation and enrolment into randomised controlled trials (RCTs) for emergency conditions. It is anticipated that there will be limited literature on this topic. This review will help evaluate the research to date on this subject, summarise current knowledge and importantly identify gaps in the literature. We hope that our results will aid in the design of future clinical trials using advanced consent.

METHODS AND ANALYSIS

Scoping review design

Given the anticipated scarcity and heterogeneity of information on this topic, a scoping review method was chosen in order to systematically assess and synthesise knowledge on advanced consent for emergency research by evaluating diverse types of research and evidence. It will help identify gaps in the literature to help guide future research. This scoping review is designed in accordance with the Preferred Reporting Items for Systematic Reviews andMeta-Analyses-Extension for Scoping Reviews (PRISMA-ScR) guidelines. It is also based on the framework initially proposed by Arksey and O'Malley,[15] and further defined by Levac.[16] As outlined, the following five steps will be used in this scoping review:

- Identifying research question.
- Identifying relevant studies.
- Selecting studies.
- Charting the data.
- Collating and summarising the results.

Research question

Prior to identifying and finalising the research question, an exploratory review of the literature surrounding advanced consent in acute neurological conditions such as status epilepticus, ischaemic stroke and ICH was completed. The search identified a small number of studies and informed the decision to broaden the search to all emergency conditions.

The main research question is as follows:

1. What work has been done applying advanced consent for participation in emergency research RCTs?

The secondary research question is as follows:

2. How has advanced consent specifically been applied to RCTs involving emergency neurological conditions, such as ICH, stroke and seizures?

Information sources and search strategy

Electronic searches will be conducted in Medline, Embase, Web of Science and the Cochrane Register of Clinical Trials. Structured search strategies will be based on controlled vocabulary and relevant key terms. Full search strategies for all databases are included in the appendix (online supplemental appendix A). Reference lists of studies selected for full-text review will be screened to ensure all original articles are captures.

Eligibility criteria

In order to effectively map key concepts and assess the breadth of knowledge in this area, most types of evidence and literature which evaluate this question will be included in our review. Based on the initial exploratory review of the literature, the inclusion and exclusion criteria were defined and are listed below:

Inclusion criteria:

- Research studies that discuss the use of advanced consent for participation in RCTs.
- Specifically related to emergency conditions and/or treatment.
- Publication types: full-text publications including qualitative and quantitative studies such as RCTs, observational studies, systematic reviews, narrative reviews and surveys; as well as ethics papers.
- Age: 18 years or older.
- Language: English.

Exclusion criteria:

- Literature focusing on advanced care planning in areas other than research such as medical care, treatment and advanced consent for end of life care.
- Non-emergency conditions, such as dementia, and non-emergent treatment.
- Other forms of consent such as deferred consent or waiver of consent.
- Publication types: letters to the editor and abstracts.
- Age and population: younger than 18 years old, pregnancy.
- Language: Non-English.

Study selection

Covidence will be used to screen citations for inclusion at the title, abstract and full text level. Covidence allows multiple users to evaluate articles for their relevance based on predefined inclusion criteria. Identified titles and abstracts will be screened independently by two trained reviewers. The reviewers will meet after 25% of the sample has been screened to resolve discrepancies. Conflicts will be resolved by consensus or a third independent reviewer. Full-text versions of potentially eligible studies will then be obtained and screened by two independent reviewers. Final inclusions will be based on the above-mentioned eligibility criteria.

Data extraction and result charting

Full texts of potentially eligible studies will be retrieved. Data will be extracted by two independent reviewers onto a standardised data charting form (online supplemental appendix B). The data charting form will be piloted on two studies and updated if needed. The results of these extractions will be compared and evaluated for inter-rater reliability prior to continuing to full data extraction.

Summary measures and data synthesis

Given the anticipated heterogeneity of study methodology of eligible studies, a narrative review with descriptive analysis will be produced. Extracted data with be synthesised using grounded theory and themes will be grouped. Interpretation will be qualitative. The analysis will map key concepts and the extent of research that has been completed on this topic. It will also identify knowledge gaps that may require further investigation.

Results and data charting

Findings will be presented according to the PRISMA-ScR reporting guidelines. Items for data extraction are listed under the data charting form (online supplemental appendix B).

PATIENT AND PUBLIC INVOLVEMENT

Patients and the public were not directly involved in the design or dissemination plan of this research project.

ETHICS AND DISSEMINATION

No research ethics board approval is required for this study as primary data will not be collected. The findings of this study will be disseminated through a peer-reviewed publication.

Acknowledgements The authors would like to acknowledge Alexandra Davis for her contribution in the developing the employed search strategies.

Contributors NN, BD, DD and MS designed the research question. NN, BD and MS designed the eligibility criteria, designed the screening strategy. BD, DD and MS designed the search strategy. NN, RL, BD and MS came up with the data extraction items and developed the data synthesis strategy. NN drafted the protocol manuscript and it was reviewed by RL, BD, DD and MS.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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